K113421

510(k) SUMMARY

Xoran Technologies, Inc.'s MiniCAT

JUL 11 2012

Sponsor/Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

Xoran Technologies, Inc.
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Contact Person: Ms. Martha J. Rumford
Regulatory Affairs Manager

Name of Device: Xoran MiniCAT™ CT Scanner

Common or Usual Name: Computed Tomography X-Ray System

Classification Name: Computed Tomography X-Ray System

Predicate Devices

Xoran Technologies, Inc., MiniCAT™ (K032243)

Purpose of the Special 510(k) notice

The MiniCAT is a modification to the cleared MiniCAT. This Special 510(k) Notice – Corrective Action Being Effected is to address certain reported software failures in the MiniCAT device. No injuries resulted from the reported failures.

Intended Use

The MiniCAT is an X-ray imaging device that constructs a three dimensional model of the head and neck from images taken during a rotational X-ray sequence. The MiniCAT is optimized for the imaging of the maxillofacial complex, temporal bone, sinuses, and for neuro-angiography.

Technological Characteristics

The MiniCAT is a dedicated X-ray imaging device that acquires a 360-degree rotation x-ray sequence of images. The MiniCAT consists of both software and hardware components. The software is used for image acquisition, processing, and viewing and consists of the following main functional units patient database, study (scan) acquisition, study reconstruction, study view, report generation, and file saving. The software also controls the hardware components of the device. The major hardware components include the X-ray source, scanning arm (motor), and detector.

The MiniCAT software has been modified as follows:

- A forced 10-minute delay has been added between scans to prevent the user from scanning during the "dwell" time.
- The software has been modified to run as a Windows shell.
- The software includes a daily calibration date checking function that displays a warning message to the user prior to scanning, if the calibration has not yet been performed that day.
- The DICOM image unique identifiers (UIDs) have been brought into compliance with the DICOM standard.

Performance Data

Verification and Validation testing were performed to support this software modification. The Xoran MiniCAT computed tomography x-ray system met all requirements and functions as intended. Thus, the modified MiniCAT is safe and effective for its intended use.

Substantial Equivalence

MiniCAT has the same intended use and similar indications, principles of operation, and technological characteristics as the predicate MiniCAT. The minor differences in the device software do not raise any new questions of safety or effectiveness. Software verification and validation testing demonstrates that the modified MiniCAT functions as intended and is as safe and effective as the predicate MiniCAT for its intended use. Thus, the MiniCAT is substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Ms. Martha J. Rumford
Regulatory Affairs Manager
Xoran Technologies, Inc.
5210 S. State Road
ANN ARBOR MI 48108

JUL 11 2012

Re: K113421
Trade/Device Name: MiniCAT
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: JAK
Dated: June 12, 2012
Received: June 13, 2012

Dear Ms. Rumford:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known):_____

Device Name: MiniCAT

Indications for Use:

The MiniCAT is an X-ray imaging device that constructs a three dimensional model of the head and neck from images taken during a rotational X-ray sequence. The MiniCAT is optimized for the imaging of the maxillofacial complex, temporal bone, sinuses, and for neuro-angiography.

Prescription Use __X___ AND/OR Over-The-Counter Use____
(Per 21 C.F.R. 801.109) (Per 21 C.F.R. 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE -- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

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